Docket No.: PF-0622 USN

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tang et al.

Title: COENZYME A-UTILIZING ENZYMES

Serial No.: 09/831,088 Filing Date: May 1, 2001

Examiner: Hutson, R. Group Art Unit: 1652

Mail Stop: Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §1.181(a) for WITHDRAWAL of the QUAYLE ACTION and REJOINDER of METHOD CLAIMS 32-34

Sir:

This is a Petition under 37 C.F.R. §1.181(a) for withdrawal of the *Ex parte Quayle* action dated April 21, 2003 and for rejoinder and examination of Applicants' method claims in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)."

I. The Examiner's Issuance of the *Ex parte Quayle* Action is Inequitable

The Examiner telephoned Applicants' Agent on April 17, 2003 to discuss claims 24-26 and 31-34. The Examiner was requesting the correction of formal matters in order to put the instant application in condition for allowance. Such matters included the cancellation of claims 32-34. Applicants' Agent brought to the Examiner's attention that method claims 32-34, which depend from

allowable claim 31 and include all the limitations of allowable claim 31, should be rejoined. The Examiner disagreed, stating that claims 32-34 are neither methods of making nor methods of using the product of claim 31. Applicants' Agent requested the Examiner to issue an Office Action to permit Applicants to rebut the Examiner's position.

On April 21, 2003, the Examiner issued an *Ex parte Quayle* action (see Office Action of April 24, 2003, page 1, Exhibit A). Applicants had received no indication during the interview that the Examiner would issue an *Ex parte Quayle* action. Accordingly, this action is premature and is inequitable since it denies Applicants of the opportunity to argue for rejoinder of method claims 32-34. By this petition, Applicants request that the *Ex parte Quayle* action be withdrawn.

II. Rejoinder of Method of Use Claims Depending From Allowable Product Claim(s) is Proper

A. Background

In response to a Restriction Requirement issued December 03, 2002, Applicants elected with traverse on January 30, 2003, to prosecute claims 23-26, 28, 30 and 31. Applicants were also required to elect a single SEQ ID NO:, and Applicants elected with traverse the polynucleotide sequence of SEQ ID NO:9. Moreover, Applicants had also requested rejoinder of claims 32-34 drawn to methods of detecting a target polynucleotide having a sequence of a polynucleotide of product claim 31. By this petition, Applicants also request rejoinder of claim 32-34. A copy of claims 31-34 can be found in the Appendix.

B. Legal Requirement

Upon allowance of an elected product claim, the requirements to be satisfied for rejoinder of method of making claims and/or method of using claims directed to the patentable product are well established.

Applicants maintain that upon allowance of any of the elected product claims, it is proper to rejoin "method of using" claims 32-34 in accordance with the Commissioner's Notice in the Official

Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)."

Applicants submit that refusal by the Office to rejoin claims 32-34 is improper. Attention is directed to the MPEP § 821.04 (Rejoinder):

> ...if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims ***which depend from*** or otherwise include all the limitations of the allowable product ***will be rejoined.*** [Emphasis added]

See also the PTO's own "Training Materials for Treatment of Product and Process Claims in Light of *In re Brouwer* and *In re Ochiai*, and 35 U.S.C. § 103(b)." Therefore, rejoinder of claims 32-34 is in keeping with the Office's own guidelines.

1. Claims 32-34 Disclose Methods for Using the Product of Claim 31

Claims 32-34 are methods for using the novel polynucleotides of claim 31 since these methods cannot be practiced without using the target polynucleotides of claim 31. Applicants' novel polynucleotides of claim 31 are essential for the uses recited in claims 32-34. Claims 32-34 use the sequences of the polynucleotides of claim 31 to detect a target polynucleotide sequence. Without knowledge of the sequences of the polynucleotides of claim 31, no probe can be known to detect the "target polynucleotides" and hence, no methods are available to detect the ***allowed product of claim 31***. Moreover, the claimed target polynucleotide sequences of claim 31 are part of the hybridization complex produced by the methods of claims 32-34, and thus are clearly used in these methods. These methods can only be practiced in conjunction with the polynucleotides of ***allowable claim 31***.

Method claims 32-34 are patentable in that they use the allowable product of claim 31 to detect the novel polynucleotide sequence of claim 31, i.e., SEQ ID NO:9, its complement and the RNA equivalents of each. Applicants emphasize that the product of claim 31 is directed to a novel full length sequence. The methods of claims 32-34, in order to be practiced, necessarily require the presence of the full length sequence of claim 31 in order for the "target polynucleotide," the polynucleotides of claim 31, to be detected, i.e., as a hybridization complex.

2. The Office has Misconstrued Claims 32-34

The Office Action has asserted that

- Knowing the sequence of the polynucleotide of claim 31 is not necessary to practice the invention of Group III (a method of detecting a polynucleotide) (Office Action of April 24, 2003, page 2).

- . . . claims 32-34 are not subject to rejoinder as they do not recite methods of using the allowable product but instead [*sic*: are] methods of using fragments of the allowable product (Office Action of April 24, 2003, page 4).

However, it is quite clear that in order to practice the methods of claims 32-34, knowledge of the product of claim 31 is required. Accordingly, claims 32-34 ***do*** require knowing the sequences of the polynucleotides of claims 31. Thus, the methods of claims 32-34 can only be practiced with the knowledge of the sequence of the target polynucleotides as recited in claim 31.

Further, the Office has asserted that claims 32-34 are methods of using fragments of the allowable product. The probe is not the point of novelty of claims 32-34; rather, the presence of a polynucleotide sequence of claim 31 imparts patentability to the method claims. Without the polynucleotide sequences of claim 31, it would not be possible to practice the methods of claims 32-34.

3. The Breadth of Claims 32-34 is of the Same Scope as Claim 31

The preamble breathes life and meaning into the claim. The preamble of claims 32 and 34 recite "[a] method of detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of **claim 31**, the method comprising . . ." Thus, claims 32-34 would include ***all*** the limitations of claim 31. That is, claims 32-34 are within the scope of claim 31.

Moreover, the Office has asserted that method claims 32-34, are directed to "methods of use of a genus of polynucleotides that were considerably broader than the elected group." However, because claims 32-34 include all the limitations of claim 31, the breadth of claims 32-34 is restricted to the claim on which they depend, i.e., claim 31. Therefore, claims 32-34 encompass and do not exceed the breadth of allowed claim 31.

4. The Office has Not Presented a *Prima facie* Case for Non-Rej inder of Claims 32-34

By misconstruing the breadth and subject matter of claims 32-34 as discussed *supra*, the Examiner has not met the burden of proof for non-rejoinder of claims 32-34. As a result, it is clear that the Examiner has not presented a *prima facie* case against rejoinder of claims 32-34. Applicants' evidence for rejoinder substantiates Applicants' position that claims 32-34 should be rejoined. Therefore, it is proper that claims 32-34 are rejoined.

C. Rejoinder of These Types of Method Claims Upon Determination of Allowable Product Claim(s) is Consistent with the Practice of Other Art Units in TC 1600

The undersigned has prosecuted numerous other applications covering the ***identical*** method of use claims which were rejoined and found allowable in TC 1600. The practice of rejoinder of method claims upon a finding of allowability of any of the product claims should be consistent within all Art Units of TC 1600. Applicants also point out that other Examiners within Group Art Units 1642 and 1652 routinely rejoin these same claims upon allowance of a product claim.

To illustrate, in Application No. USSN 09/519,283, the Notice of Allowability mailed May 6, 2003 indicated polynucleotide product claim 29 and method claims which depend from claim 29, claims 31-33 (identical to claims 32-34) as allowable (Exhibit C, Notice of Allowability mailed May 6, 2003, USSN 09/519,283, Art Unit 1652, pages 1-3, and a copy of claims 29 and 31-33, as amended). It should be noted that Art Unit 1652 is the same art unit as the subject petition.

In another example, Application No. USSN 09/802,741, the Office Action of April 24, 2003 indicated claim 11 as directed to an allowable product (polynucleotides) and the Office rejoined and allowed method claims 13-15 (identical to claims 32-34) and claim 21, all of which depend from claim 11 (Exhibit B, Office Action of April 24, 2003, USSN 09/802,741, pages 1-3, and a copy of claims 11, 13-15 and 21).

Clearly, as the two allowed applications illustrate *supra*, the Office followed the procedures set forth in th Official Gazette Notice dated March 26, 1996 (1184 O.G. 86) and the courts' rulings in *In re Ochiai and In re Brouwer* by rejoining the method claims. It is Applicants' position that in a

substantial majority of applications containing claims of an ***identical*** nature to patentably distinct gene sequences, rejoinder of method claims ***identical*** to claims 32-34, such as claims 31-33 of USSN 09/519,283 and claims 13-15 of USSN 09/802,741, is otherwise consistent with the procedures set forth by the Commissioner in the Official Gazette and routinely practiced by the Office.

III. Conclusion

Applicants submit that the prosecution of this application is not complete and that the *Ex parte Quayle* action is premature and should be withdrawn. The practice of the methods of claims 23-34 could not occur until Applicants provided the novel polynucleotide sequence of SEQ ID NO:9. It would not be possible for one of skill in the art to identify a probe which would detect the polynucleotides of claim 31 without SEQ ID NO:9. Claims 32-34 are novel methods for using the novel polynucleotides of claim 31 in the detection of the novel polynucleotide sequences of claim 31. Thus, it is proper to rejoin method of use claims 32-34 which depend from allowable product claim 31.

Therefore, for all the reasons provided *supra* and in accordance with the examples provided, Applicants request withdrawal of the *Ex parte Quayle* action, and rejoinder and examination of claims 32-34 in the instant application in keeping with the procedures as set forth in the Official Gazette Notice dated March 26, 1996 (1184 O.G. 86) and the USPTO's own "Training Materials for Treatment of Product and Process Claims in Light of *In re Ochiai and In re Brouwer*" and 35 U.S.C. § 103(b). Consistency of practice within the Office is paramount to the tenets of patent protection which Applicants seek.

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Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108. This form is enclosed in duplicate.**

Respectfully submitted,

INCYTE CORPORATION

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Attachments:
Exhibit A - Office Action Summary of 4/24/03, USSN 09/831,088, including Interview Summary of 4/17/03.
Exhibit B - Office Action of 4/24/03, USSN 09/802,741, pp. 1-3, and claims 11, 13-15 and 21.
Exhibit C - Notice of Allowability of 5/6/03, USSN 09/519,283, pp. 1-3, and claims 29 and 31-33.